

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO  
ALL CLASS ACTIONS

**AMGEN INC.'S ANSWER TO PLAINTIFFS' SECOND AMENDED  
MASTER CONSOLIDATED CLASS ACTION COMPLAINT**

Defendant Amgen Inc. ("Amgen"), hereby answers the allegations set forth in Plaintiffs' Second Amended Master Consolidated Class Action Complaint (the "SAMCC"), and for its answer, states and alleges as follows:

**Preface**

To the extent that the SAMCC makes allegations that refer to the knowledge, conduct or actions of others, Amgen is generally without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations and, on that basis, denies those allegations.

The SAMCC improperly mixes factual allegations with vague and conclusory allegations, making it impossible for Amgen to prepare a meaningful response to such allegations. The SAMCC also includes undefined terms that are susceptible of different meanings. In addition, the SAMCC contains purported quotations from a number of different sources, many of which are unidentified. In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or

entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

Amgen denies each and every factual allegation contained in the SAMCC, except as specifically admitted herein. Amgen specifically denies any allegations contained in headings, footnotes, the Table of Contents or unnumbered paragraphs in the SAMCC.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

## **I. INTRODUCTION**

1. Amgen admits that Plaintiffs seek to bring this action as alleged in Paragraph 1 of the SAMCC. Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged.

2. Amgen denies the existence of, or its participation in, any “conspiracy” as alleged in Paragraph 2 of the SAMCC. To the extent the allegations in Paragraph 2 of the SAMCC allege a conspiracy between Amgen and various publishing entities, no response is required because these allegations, which formed the basis of Count I of the Amended Master Consolidated Complaint (“AMCC”), have been dismissed with prejudice by the Court. To the extent the allegations in Paragraph 2 of the SAMCC refer to the knowledge, conduct or actions of persons or entities other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, these allegations are denied.

3-4. As to Paragraphs 3 and 4 of the SAMCC, Amgen admits that it has manufactured or distributed certain pharmaceutical products that are covered under Medicare Part B, and that at certain times, Congress mandated that Medicare Part B reimbursement for some of these

products be based in part upon AWP, and that some Medicare Part B medicines generally are administered in a healthcare provider's office. Amgen admits that it reports certain information for its products to independently published pharmaceutical industry publications. Amgen admits that AWP benchmarks published in these trade publications can be higher than the prices ultimately paid by providers. Amgen denies the remaining allegations in these paragraphs that pertain to it.

5. Amgen denies the existence of, and its participation in, any "AWP scheme" as alleged in Paragraph 5 of the SAMCC. To the extent the allegations in Paragraph 5 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, these allegations are denied. Amgen denies the remaining allegations in Paragraph 5 of the SAMCC that pertain to it.

6. To the extent the allegations in Paragraph 6 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, these allegations are denied. Amgen admits that Plaintiffs purport to bring this action as alleged in Paragraph 6 of the SAMCC, but Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged. Amgen denies the remaining allegations in Paragraph 6 of the SAMCC that pertain to it.

7. Amgen denies the existence of, and its participation in, any "high profit scheme" as alleged in Paragraph 7 of the SAMCC. To the extent the allegations in Paragraph 7 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or

falsity of those allegations and for this reason, these allegations are denied. Amgen denies the remaining allegations in Paragraph 7 of the SAMCC that pertain to it.

8. Amgen denies the existence of, and its participation in, any “scheme” or “unlawful agreement” as alleged in Paragraph 8 of the SAMCC. To the extent the allegations in Paragraph 8 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, these allegations are denied. Amgen denies the remaining allegations in Paragraph 8 of the SAMCC that pertain to it.

9-10. Paragraphs 9 and 10 of the SAMCC contain allegations directed to parties other than Amgen, and thus require no response. To the extent that a response is deemed required, those allegations are denied.

11. Amgen admits that Plaintiffs have filed attachments to the SAMCC. To the extent the allegations in Paragraph 11 of the SAMCC are deemed to include allegations against Amgen, they are denied.

12. Because the Court dismissed Count I in its February 24, 2004 memorandum and order, no response is required. To the extent that a response is deemed required, Amgen denies the allegations in Paragraph 12 and in Count I of the SAMCC.

13-21. Amgen denies the existence of, or its participation in, any “enterprise,” “scheme” or “conspiracy” as alleged in Paragraphs 13 through 21 of the SAMCC. Amgen admits that Plaintiffs purport to bring this action as a class action, and that Plaintiffs seek relief under Counts II through X as alleged in Paragraphs 13 through 21 of the SAMCC. Amgen denies that this action can be maintained in the manner alleged, and further denies that Plaintiffs are entitled to

relief under Counts II through X of the SAMCC. Except as specifically admitted herein, the factual allegations against Amgen set forth in these paragraphs are denied.

## **II. JURISDICTION AND VENUE**

22. Amgen admits that this Court has subject matter jurisdiction, subject to the political question and other defenses raised below. Upon information and belief, Amgen admits that this Court has diversity jurisdiction. Except as specifically admitted herein and to the extent that the remaining allegations are deemed to require a response by Amgen, Amgen denies those allegations.

23. Admitted.

24. Amgen admits that venue is proper in this jurisdiction for purposes of pretrial proceedings as alleged by Plaintiffs, but denies that venue is proper in this jurisdiction for trial or other non-MDL purposes. To the extent that the remaining allegations in Paragraph 24 are directed at Amgen, those allegations are denied, and Amgen specifically denies the existence of, and its participation in, any alleged “fraudulent marketing scheme.” To the extent that the allegations in Paragraph 24 refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, they are denied.

25. Admitted.

## **III. PARTIES**

26-31. Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraphs 26 through 31 of the SAMCC and for this reason, these allegations are denied.

32-36. Amgen admits that Plaintiffs VPIRG, WCA, StateWide, CANY and CCJ purport to bring this action as alleged in Paragraphs 32 through 36 of the SAMCC, but denies that these Plaintiffs have standing to bring the alleged action. Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraphs 32 through 36, including Paragraphs 36(a)-(c), and for this reason, these allegations are denied.

37-38. To the extent the allegations in Paragraphs 37 through 38 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, these allegations are denied. Amgen denies the remaining allegations in Paragraphs 37 through 38 of the SAMCC that pertain to it, and specifically denies the existence of, or its participation in, any “conspiracy” as alleged.

39-41. The allegations in Paragraphs 39 through 41 of the SAMCC are not directed to Amgen, and thus require no response. To the extent that a response is deemed required, Amgen denies these allegations.

42-43. Amgen admits it is a Delaware corporation with its principal place of business located at One Amgen Drive, Thousand Oaks, California. Amgen further admits that it is in the business of researching, developing, manufacturing and marketing biologics and other pharmaceutical products, including products that are reimbursed under Medicare Part B. Amgen also admits that it manufactures Epogen® and Neupogen®.

44-131. The allegations set forth in Paragraphs 44-131 of the SAMCC are not directed at Amgen and thus require no response. To the extent that a response is deemed required, the allegations set forth in these paragraphs are denied.

**IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS**

132. To the extent the allegations in Paragraph 132 of the SAMCC are directed to other defendants, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, these allegations are denied. Amgen denies the allegations in Paragraph 132 of the SAMCC that pertain to it.

133. Upon information and belief, Amgen admits the allegations in Paragraph 133 of the SAMCC.

134. Amgen admits that the Medicare Part B program used AWP as one factor in setting payment allowances for many reimbursed drugs. Except as otherwise admitted herein, Amgen denies the remaining allegations set forth in this paragraph that pertain to Amgen.

135. Amgen admits that there are several independently produced and published pharmaceutical industry compendia that periodically publish AWP and other information. Except as otherwise admitted herein, Amgen denies the remaining allegations set forth in this paragraph that pertain to Amgen.

136. To the extent that the allegations set forth in Paragraph 136 are directed at Amgen, those allegations are denied.

137-141. To the extent the allegations in Paragraphs 137 through 141 of the SAMCC refer to the knowledge, conduct, opinions or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen specifically denies the existence of, or any participation in, any “scheme to generate the profit spread” or any “AWP scheme” as alleged in these paragraphs.

142-144. Admitted.

145. Amgen admits that the general reimbursement methodology for drugs covered by Medicare Part B is set forth in 42 C.F.R. § 405.517, the terms of which speak for themselves. Amgen is otherwise without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, they are denied.

146. Amgen denies the allegations in the first sentence of Paragraph 146 of the SAMCC insofar as the source of the quoted material is unidentified. Amgen denies the second sentence of Paragraph 146 of the SAMCC insofar as 42 C.F.R. § 405.517 contains no reference to a “ceiling” on reimbursement amounts.

147. Amgen admits that 42 C.F.R. § 405.517 was amended, and that the terms of the amended provision speak for themselves.

148. Amgen admits that Medicare has announced its use of AWP in connection with reimbursement. The terms of the cited Program Memorandum (AB-99-63) speak for themselves. Amgen denies any remaining factual allegations set forth in this paragraph.

149. Program Memo AB-99-63, cited in Paragraph 149 of the SAMCC, speaks for itself. Amgen denies any and all remaining allegations in this paragraph that are directed at Amgen.

150. The allegations set forth in Paragraph 150 contain legal conclusions to which no response is required. In addition, the provisions of Medicare Part B speak for themselves. To the extent that a response is deemed required, any factual allegations directed at Amgen are denied.

151. Upon information and belief, the allegations set forth in Paragraph 151 of the SAMCC are admitted.

152. To the extent the allegations in Paragraph 152 of the SAMCC refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, they are denied. Amgen admits that it reports certain information for its products to independent pharmaceutical publications. Amgen denies any remaining allegations in Paragraph 152 of the SAMCC that pertain to it.

153-154. The April 2003 OIG publication cited in Paragraphs 153 through 154 of the SAMCC speaks for itself. Amgen denies that Plaintiffs have accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that they are in any way applicable to Amgen.

155. To the extent the allegations in Paragraph 155 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations and, therefore, denies those allegations. Amgen denies the remaining allegations in Paragraph 155 of the SAMCC that pertain to it.

156-157. Amgen denies the existence of, and its participation in, any "scheme" cited in Paragraph 156 of the SAMCC. Amgen states that the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 156 through 157 of the SAMCC speaks for itself. Amgen denies that Plaintiffs have accurately characterized any findings, opinions, statements or conclusions of Congressman Stark, or that they are in any way applicable to Amgen.

158-159. To the extent the allegations in Paragraphs 158 through 159 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen,

Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen denies the remaining allegations in Paragraphs 158 through 159 of the SAMCC that pertain to it. Amgen further denies the existence of, and its participation in, any “scheme” as alleged in Paragraph 159 of the SAMCC.

160. To the extent the allegations in Paragraph 160 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen admits that it provided suggested AWPs for its products to independently produced publications.

161-184. To the extent the allegations in Paragraphs 161 through 184 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen denies the remaining factual allegations in Paragraphs 164 through 184 of the SAMCC that pertain to it. Amgen denies the existence of, and its participation in, any “scheme” as alleged in Paragraphs 161 and 163 of the SAMCC.

185. Amgen admits that Plaintiffs purport to quote from an unidentified “industry consultant” as alleged in Paragraph 185 of the SAMCC, but Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 185 of the SAMCC, and for this reason, those allegations are denied.

186-191. To the extent the allegations in Paragraphs 186 through 191 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen,

Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. The *Red Book* and the unidentified “DOJ Determined Actual AWP” cited in Paragraph 187 of the SAMCC and pleadings cited in Paragraphs 189 through 190 of the SAMCC speak for themselves. To the extent the allegations in Paragraphs 186 through 191 of the SAMCC are deemed to include allegations against Amgen, they are denied.

192. To the extent the allegations in Paragraph 192 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations and for this reason, those allegations are denied. The 2003 CMS document cited in Paragraph 192 of the SAMCC speaks for itself. Amgen denies that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement or conclusion. Amgen admits that some of its products compete with other products and that Amgen seeks to protect confidential and proprietary business information relating to its products. Amgen denies the remaining allegations in Paragraph 192 of the SAMCC that pertain to it.

193-196. To the extent the allegations in Paragraphs 193 through 196 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen denies the allegations in Paragraphs 193 through 196 of the SAMCC that pertain to it.

197. In response to the allegations in Paragraph 197 of the SAMCC, Amgen denies that Plaintiffs lacked inquiry or other notice of the issues associated with reliance on AWP in

connection with reimbursement. To the contrary, Amgen states that such issues were well known for more than a decade before Plaintiffs elected to bring this suit.

198-199. The allegations in Paragraphs 198 through 199 of the SAMCC state legal conclusions to which no response is required. To the extent a response is required, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations in Paragraphs 198 through 199 of the SAMCC that refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, and for this reason, those allegations are denied. Amgen denies the remaining allegations in Paragraphs 198 through 199 of the SAMCC that pertain to it.

#### **V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT**

200. To the extent the allegations in Paragraph 200 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen denies the remaining allegations in Paragraph 200 of the SAMCC that pertain to it.

201-216. The allegations in Paragraphs 201 through 216 of the SAMCC are directed to parties other than Amgen and thus require no response. To the extent that a response is deemed required, the allegations in Paragraphs 201 through 216 of the SAMCC are denied.

217. Amgen denies the allegations set forth in Paragraph 217, although Amgen admits that the SAMCC purports to seek relief in connection with the various Amgen products identified in this paragraph.

217A. Amgen admits it introduced EpoGen® in 1989 and that EpoGen® is indicated for the treatment of anemia in patients with chronic renal failure on dialysis. Amgen admits that Aranesp is an erythropoietic protein with a longer half-life than Epoetin alfa, which leads to

greater biological activity. Amgen admits Aranesp was approved in September 2001 for the treatment of anemia in patients with chronic renal failure and that in July 2002, the FDA approved Aranesp for use in the treatment of chemotherapy-induced anemia in patients with nonmyeliod malignancies. Aranesp's U.S. sales for 2002 were \$284.7 million.

217B. Admitted.

218. Denied.

218A. To the extent that Paragraph 218A refers to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. To the extent Paragraph 218A references Amgen's website, the content of the website speaks for itself. Amgen denies the remaining factual allegations that pertain to it.

218B. The allegations in Paragraph 218B are directed to parties other than Amgen and thus require no response. Amgen further states that Ortho Biotech's website speaks for itself. To the extent that a response is deemed required, the allegations in Paragraph 218B are denied.

219. Denied.

219A. Denied.

219B. Denied. To the extent Paragraph 219B cites to Amgen's website, the website speaks for itself.

220. Denied.

220A. The excerpt quoted in Paragraph 220A of the SAMCC speaks for itself. Amgen denies the remaining factual allegations set forth in this paragraph.

220B. Denied.

221. The unattributed comment quoted in Paragraph 222 of the SAMCC speaks for itself. Amgen denies the remaining factual allegations set forth in this paragraph.

221A. Denied.

221B. Amgen admits that it has established a website to help providers having questions concerning, among other things, reimbursement for Amgen products, and has also established a Reimbursement Hotline for similar purposes.

222. Denied. The excerpt quoted in Paragraph 222, which purports to be from Amgen's website, speaks for itself.

222A. Denied.

222B. Denied.

223. Denied.

223A. Denied.

223B. Denied.

224. Denied.

224A. Denied.

224B. To the extent that the allegations of Paragraph 224B refer or relate to the knowledge, conduct, opinions or actions of persons, entities, or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations and for this reason, the allegations are denied. To the extent the allegations refer or relate to Amgen, the allegations are denied.

225. Denied.

225A. Denied.

225B. To the extent the allegations in Paragraph 225B refer or relate to the knowledge, conduct, opinions or actions of persons, entities, or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen denies the allegations in Paragraph 225B that pertain to it.

226. Denied.

226A. Denied.

226B. Denied.

227. Denied.

227A. Denied.

227B. Denied.

228. The OIG report cited in Paragraph 225 of the SAMCC speaks for itself. Amgen denies that Plaintiffs have accurately characterized any alleged finding, opinion, statement or conclusion set forth in that report.

228A. Denied.

229. Denied.

229A. Denied.

230. To the extent that the allegations of Paragraph 230 refer or relate to Amgen's product, EpoGen®, the allegations are denied. By way of further response, Amgen admits that the GAO report, the terms of which speak for itself, identifies Epoetin alfa for non-ESRD use (i.e., Procrit®), as accounting for approximately 9.5% of spending for prescription drugs by Medicare.

230A. Denied.

231-540. The allegations in Paragraphs 231 through 540 of the SAMCC are directed to parties other than Amgen and thus require no response. To the extent that a response is deemed, the allegations set forth in Paragraphs 231 through 540 of the SAMCC are denied.

**VI. DIRECT DAMAGE SUSTAINED BY PLAINTIFFS AND THE MEMBERS OF THE AWP CLASS**

541. Amgen denies that Plaintiffs have suffered damages or injuries as alleged in Paragraph 541 of the SAMCC. Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 541 of the SAMCC and, therefore, denies those allegations.

**VII. PLAINTIFFS' CLAIMS CONCERNING TOGETHER RX TO FIX PRICES—THE TOGETHER CARD SCHEME**

542-594. The allegations in Paragraphs 542 through 594 are directed to parties other than Amgen and thus require no response. To the extent that a response is deemed, the allegations in Paragraphs 542 through 594 of the SAMCC are denied.

**VIII. CLASS ACTION ALLEGATIONS FOR THE PURPORTED “AWP PAYOR CLASS”**

595-598. Amgen admits that Plaintiffs purport to bring this action as alleged in Paragraphs 595 through 598 of the SAMCC, but denies that Plaintiffs are entitled to maintain this action in the manner alleged. Amgen denies that Plaintiffs or any putative class members have suffered damages as alleged in Paragraph 598 of the SAMCC.

599-603. The allegations in Paragraphs 599 through 603 of the SAMCC set forth legal conclusions to which no response is required. To the extent that a response is deemed required, those allegations are denied. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives and that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraph 603 of the SAMCC.

**IX. CLASS ALLEGATIONS FOR THE PURPORTED “TOGETHER RX CLASS”**

604-618. The allegations set forth in Paragraphs 604 through 618 of the SAMCC are directed at parties other than Amgen and thus require no response. To the extent that a response is deemed required, the allegations set forth in these paragraphs are denied.

**COUNT I (RICO)**

619-646. The Court has dismissed Count I in its February 24, 2004 memorandum and order with prejudice. Accordingly, no response by Amgen is required. To the extent that a response is deemed required, the allegations set forth in these paragraphs are denied.

**COUNT II (RICO)**

647. Amgen repeats and realleges its responses to Paragraphs 1 through 646 of the SAMCC as if fully set forth herein.

648. To the extent the allegations in Paragraph 648 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen admits that Plaintiffs purport to bring this action and to seek relief under Count II of the SAMCC as alleged in Paragraph 648, but Amgen denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Amgen under Count II. Amgen denies the remaining allegations in Paragraph 648 of the SAMCC.

649. The allegations in Paragraph 649 of the SAMCC set forth legal conclusions to which no answer is required. To the extent that a response is deemed required, these allegations are denied. Amgen further denies that Plaintiffs have pled a proper class.

650. To the extent the allegations in Paragraph 650 of the SAMCC and subparts set forth legal conclusions, no answer is required. To the extent that a response is deemed required, these allegations are denied. Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 650 and its subparts and, therefore, denies those allegations.

651-655. Amgen denies the existence of, or its participation in, any “enterprise,” “AWP Scheme,” or “hidden-profit scheme” as alleged in Paragraphs 651 through 655 of the SAMCC. To the extent the allegations in Paragraphs 651 through 655 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. The unidentified “industry report” cited in Paragraph 655 of the SAMCC speaks for itself. Amgen denies that Plaintiffs have accurately characterized any alleged “industry report” finding, opinion, statement or conclusion. Amgen denies the remaining allegations in Paragraphs 651 through 655 that pertain to it.

656-678. Amgen denies the existence of, or its participation in, any “enterprise,” “AWP spread scheme,” “AWP Scheme,” “The Amgen Manufacturer-PBM Enterprise” and/or “Manufacturer-PBM Enterprise” as alleged in Paragraphs 656 through 678 of the SAMCC. To the extent the allegations in Paragraphs 656 through 678 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. To the extent the allegations in Paragraph 656 through 678 of the SAMCC include allegations against Amgen, they are denied, and Amgen specifically denies the allegations set forth in subparagraph (b) of Paragraph 661 of the SAMCC.

679. The allegations in Paragraph 679 of the SAMCC set forth legal conclusions to which no response is required. To the extent that a response is deemed required, these allegations are denied.

**COUNT III (DECLARATORY RELIEF)**

680. Amgen repeats and realleges its responses to Paragraphs 1 through 679 of the SAMCC as if fully set forth herein.

681. The allegations in Paragraph 681 of the SAMCC set forth legal conclusions to which no response is required. To the extent that a response is deemed required, Amgen denies that Plaintiffs have standing to bring this action, and denies that an actual case and controversy exists. To the extent the allegations in Paragraph 681 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen denies any remaining allegations in Paragraph 681 of the SAMCC that pertain to it.

682-683. Amgen refers to and incorporates its response to Paragraph 681 of the SAMCC. To the extent the allegations in Paragraphs 682 through 683 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen denies the remaining allegations in Paragraphs 682 through 683 of the SAMCC that pertain to it.

**COUNT IV (CONSUMER PROTECTION STATUTES)**

684. Amgen repeats and realleges its responses to Paragraphs 1 through 683 of the SAMCC.

685. Amgen admits that Plaintiffs purport to bring this action and seek relief under Count IV of the SAMCC as alleged in Paragraph 685, but denies that Plaintiffs are entitled to maintain this action as alleged or are entitled to any relief against Amgen under Count IV. Amgen denies the remaining allegations in Paragraph 685 of the SAMCC.

686. To the extent the allegations in Paragraph 686 of the SAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen admits that its principal place of business is located in California. Amgen admits that certain states have enacted consumer protection laws, but denies that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. Amgen denies the remaining allegations in Paragraph 686 of the SAMCC that pertain to it.

687-691. Amgen denies the existence of, and its participation in, any “AWP Scheme” as alleged in Paragraph 687 of the SAMCC. To the extent the allegations in Paragraphs 687 through 691 of the SAMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen denies the remaining allegations in Paragraphs 687 through 691 of the SAMCC and subparts that pertain to it. Amgen further denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 689 and 691 of the SAMCC.

**COUNT V (CLAYTON ACT – TOGETHER RX)**

692. Amgen repeats and realleges its responses to Paragraphs 1 through 691 of the SAMCC as if fully set forth herein.

693-698. The allegations set forth in Paragraphs 693 through 698 are directed to parties other than Amgen and thus require no response. To the extent that a response is deemed required, Amgen denies these allegations.

**COUNT VI (SHERMAN ACT)**

699. Amgen repeats and realleges its responses to Paragraphs 1 through 698 if the SAMCC as if fully set forth herein.

700-704. The allegations set forth in Paragraphs 700 through 704 are directed to parties other than Amgen and thus require no response. To the extent that a response is deemed required, Amgen denies these allegations.

**COUNT VII (INDIRECT PURCHASER – TOGETHER RX)**

705. Amgen repeats and realleges its responses to Paragraphs 1 through 704 of the SAMCC as if fully set forth herein.

706-708. The allegations set forth in Paragraphs 706 through 708 of the SAMCC are directed to parties other than Amgen and thus require no response. To the extent that a response is deemed required, Amgen denies these allegations.

**COUNT VIII (RICO – TOGETHER RX)**

709. Amgen repeats and realleges its responses to Paragraphs 1 through 708 of the SAMCC as if fully set forth herein.

710-725. The allegations set forth in Paragraphs 710 through 725 of the SAMCC are directed to parties other than Amgen and thus require no response. To the extent that a response is deemed required, Amgen denies these allegations.

**COUNT IX (CIVIL CONSPIRACY – PBM<sub>s</sub>)**

726. Amgen repeats and realleges its responses to Paragraphs 1 through 725 of the SAMCC as if fully set forth herein.

727. Amgen admits that Plaintiff CMHV purports to bring this action as alleged in Paragraph 727 of the SAMCC, but denies that Plaintiff CMHV is entitled to maintain this action in the manner alleged or that CMHV is a proper class representative. Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 727 of the SAMCC, and for this reason, those allegations are denied.

728-731. Amgen denies the existence of, and its participation in, any “scheme,” “AWP Scheme,” “conspiracy” or “The Amgen Group Manufacturer-PBM Conspiracies” as alleged in Paragraphs 728 through 731 of the SAMCC. To the extent the allegations in Paragraphs 728 through 731 of the SAMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations, and for this reason, those allegations are denied. Amgen denies the remaining allegations in Paragraphs 728 through 731 of the SAMCC and subparts that pertain to it, and Amgen specifically denies the allegations set forth in subparagraph (b) of Paragraph 728 of the SAMCC.

732-733. Amgen denies the allegations in Paragraphs 732 through 733 of the SAMCC, and specifically denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraph 733 of the SAMCC.

**COUNT X. (CIVIL CONSPIRACY – TOGETHER RX)**

734. Amgen repeats and realleges its responses to Paragraphs 1 through 733 of the SAMCC as if fully set forth herein.

735-741. The allegations set forth in Paragraphs 735 through 741 of the SAMCC are directed to parties other than Amgen and thus require no response. To the extent that a response is deemed required, these allegations are denied.

**UNNUMBERED “WHEREFORE” PARAGRAPH  
AND REQUEST FOR JURY TRIAL**

Amgen denies Plaintiffs are entitled to a judgment or any other relief requested in their Prayer for Relief and “WHEREFORE” paragraph following Paragraph 741 of the SAMCC.

**DEFENSES**

Without assuming any burden that it would not otherwise have, and without waiving any denial asserted herein, Amgen further responds to the SAMCC by stating and alleging as follows:

1. The Complaint fails to state a claim upon which relief may be granted.
2. Amgen has not acted in a manner that is illegal, oppressive, or fraudulent and in fact acted in good faith, with just cause, and in accordance with established industry practices and government requirements and policies.
3. The federal government adopted AWP with knowledge that it was not a calculation of actual average prices and with no express or implicit definition contrary to industry practice. For public policy and other reasons, the federal government retained AWP in the face of years of criticism that it

was not a calculation of actual average prices. Among the defenses that arise from those and other relevant circumstances are the following:

- A. Plaintiffs' claims are barred, in whole or in part, by the political question, separation of powers, and filed rate doctrines. The relief sought by plaintiffs would interfere with legislative decisions and functions.
- B. Plaintiffs' claims are barred, in whole or in part, because Amgen has complied with all applicable statutes and regulations.
- C. Plaintiffs' claims are barred, in whole or in part, because they violate Amgen' rights under the Due Process and Ex Post Facto clauses of the United States Constitution, as well as all applicable state constitutions, insofar as, among other things, Plaintiffs and the putative class members seek to impose liability under vague or nonexistent standards or seek to impose liability retroactively for conduct that was not actionable at the time it occurred.
- D. Plaintiffs' claims are barred, in whole or in part, because Amgen did not make any false statements to Plaintiffs or to any members of the putative class members. Amgen had no reasonable grounds to believe, and did not believe, that any statement was false or misleading or capable of being false or misleading.
- E. The communications and conduct of Amgen and others are protected by the First Amendment, applicable state constitutions, and common law privileges, and it would violate those protections to construe AWP as fraudulent.

F. Plaintiffs' claims are barred, in whole or in part, by the government contractor and similar defenses because the reimbursement system, including the use of AWP in excess of actual average prices, was designed and approved by the United States Government to serve its purposes.

G. Amgen relied on the policies and practices of the federal and state governments, and plaintiffs are estopped or otherwise barred from seeking to impose liability for such reliance.

H. Plaintiffs' approach to AWP would discourage legitimate price competition and is inconsistent with and preempted by the Sherman Act.

I. Plaintiffs' claims are barred, in whole or in part, because, *inter alia*, in directly or indirectly adopting "AWP" outside of its government reimbursement and industry context plaintiffs acted recklessly and assumed all risks that they or their representatives might not understand it properly, because they are bound by the government's knowledge and purposes, and because they consented to and ratified use of AWP.

4. Plaintiffs' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, regulations promulgated under those acts, and by the dormant Commerce Clause of the United States Constitution.

5. Plaintiffs' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or expressive conduct by Amgen, healthcare providers, or

others directed at judicial, legislative, or administrative bodies of government.

6. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and repose.
7. Plaintiffs' claims are barred, in whole or in part, by the doctrines of laches, estoppel, and waiver.
8. Plaintiffs lack standing and privity.
9. Amgen denies that Plaintiffs and the putative class have met the statutory and case law requirements of state consumer protection acts. However, if such claims are found to exist, Amgen pleads all available defenses under the Acts, including standing, lack of direct purchaser, federal preemption, and lack of consumer status or involvement.
10. Plaintiffs' claims for declaratory or equitable relief are barred because plaintiffs have an adequate remedy at law, because the claims were rendered moot by the passage of the 2003 Medicare reform legislation, and due to the doctrine of *in pari delicto* or unclean hands.
11. Plaintiffs' claims are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price because third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums or in other ways; because such supracompetitive price, if any, was absorbed, in whole or part, by a person or entity that purchased the medicine directly, or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class

members; or because purchasers who paid directly or indirectly on the basis of an allegedly excessive AWP would have paid more with respect to this or other elements of health care pricing in the absence of AWP.

12. To the extent Plaintiffs or any member of the putative class obtain or have obtained recovery or have benefited from another entity's recovery in this or any other case or through any other method predicated on the same factual allegations, that Plaintiff or purported class member is barred from seeking recovery against Amgen based on the SAMCC.
13. Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction, or otherwise compromised their claims.
14. Plaintiffs' claims are barred, in whole or in part, due to their failure to join indispensable parties.
15. Plaintiffs' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superceding conduct of third parties or of the plaintiffs or their agents or representatives.
16. Plaintiffs' claims are barred, in whole or in part, because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.
17. Plaintiffs' claims are barred, in whole or in part, because they failed to mitigate their damages, and their failure to mitigate damages should

proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Amgen.

18. Plaintiffs' claims are barred, in whole or in part, because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the SAMCC.
19. Amgen is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs or the putative class, with respect to the same alleged injuries.
20. Any damages recovered by the Plaintiffs and the putative class from Amgen must be limited by any applicable statutory ceilings on recoverable damages.
21. Any punitive damages would be excessive, penal in nature, and would subject Amgen to multiple and retroactive liability and would deny Amgen constitutionally adequate standards, instructions, and procedures.
22. Plaintiffs' claims for punitive damages are barred by federal and state constitutions, common law, and public policies.
23. Maintenance of this action as a class action would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch.
24. Maintenance of this action as a class action and in one proceeding against many defendants would violate Amgen's rights as provided by the Federal and state constitutions by denying Amgen procedural and substantive safeguards.

25. Plaintiffs' claim for punitive and other damages against Amgen cannot be sustained because any award without the apportionment of the award separately and severally between or among the defendants and other alleged responsible parties, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Amgen's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law, and public policies of any applicable state.
26. Plaintiffs are not the real parties in interest.
27. Amgen maintained policies regarding samples, grants, and other issues that prohibited unlawful practices and trained its relevant employees regarding such policies.
28. Plaintiffs' claims are barred, in whole or in part, under principles relating to conflict of laws.
29. Plaintiffs' claims are barred, in whole or in part, by operation of the Full Faith and Credit Clause.
30. Plaintiffs' claims under various state consumer protection statutes are barred, in whole or in part, by principles relating to the extraterritorial application of such provisions.
31. Amgen adopts by reference any additional applicable defense pled by any other defendant not otherwise pled in this answer. Amgen hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the

discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense. Amgen also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part of it, is governed by the substantive law of a state other than California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, and Washington.

**PRAYER FOR RELIEF**

WHEREFORE, Defendant Amgen Inc. requests the following relief:

- A. Dismissal of Plaintiffs' claims with prejudice;
- B. An award of attorneys' fees and costs; and
- C. Such other legal and equitable relief as the Court deems proper.

Respectfully submitted,

/s/ Douglas S. Brooks  
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March 17, 2005

**CERTIFICATE OF SERVICE**

I hereby certify that on this 17th day of March, 2005, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to Verilaw Technologies for posting and notification.

/s/ Douglas S. Brooks

Douglas S. Brooks